

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61F 2/44, 2/46	A1	(11) International Publication Number: WO 00/23015 (43) International Publication Date: 27 April 2000 (27.04.00)
(21) International Application Number: PCT/US98/22436		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 22 October 1998 (22.10.98)		
(71) Applicant: SDGI HOLDINGS, INC. [US/US]; 300 Delaware Avenue, Suite 508, Wilmington, DE 19801 (US).		
(74) Agents: BROWN, Christopher, A. et al.; Woodard, Emhardt, Naughton, Moriarty & McNett, Suite 3700, Bank One Center/Tower, 111 Monument Circle, Indianapolis, IN 46204 (US).	Published <i>With international search report.</i>	
(54) Title: ARTIFICIAL INTERVERTEBRAL JOINT PERMITTING TRANSLATIONAL AND ROTATIONAL MOTION		
(57) Abstract		
An intervertebral joint prosthesis (20) having a ball component (22) for engagement with a first vertebra (26) and a trough component (24) for engagement with a second vertebra (27) adjacent to the first vertebra (26) is disclosed. The trough component (24) includes a generally concave surface (50) having a substantially flat portion (52). When the ball component (22) and the trough component (24) are engaged to their respective vertebrae (26, 27), the ball component (22) and the trough component (24) engage each other, permitting rotation and translation of the vertebrae (26, 27) with respect to each other. Both components (22, 24) include a flange (34, 56) for engaging a vertebra (26, 27). The invention also contemplates a tool (70) for use in implanting a two-piece intervertebral joint prosthesis (20).		

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

ARTIFICIAL INTERVERTEBRAL JOINT PERMITTING TRANSLATIONAL AND ROTATIONAL MOTION

FIELD OF THE INVENTION

10 The present invention is directed to an intervertebral joint prosthesis. Specifically, the invention includes a device which is implanted in place of degenerated or absent intervertebral disc tissue, and tools and methods for implanting the same.

15.

BACKGROUND OF THE INVENTION

In the treatment of diseases, injuries or malformations affecting spinal motion segments (which include two adjacent vertebrae and the disc tissue or disc space between them), and especially those affecting disc tissue, it has long been known to remove some or all of a degenerated, ruptured or otherwise failing disc. In cases in which intervertebral disc tissue is removed or is otherwise absent from a spinal motion segment, corrective measures are indicated to insure the proper spacing of the vertebrae formerly separated by the removed disc tissue.

25 Commonly, the two vertebrae are fused together using transplanted bone tissue, an artificial fusion element, or other compositions or devices. Fusion of adjacent vertebrae is a procedure that is performed many tens of thousands of times each year in the United States and Canada.

There is increased concern in the spinal medical community, however, that 30 the biomechanical rigidity of the intervertebral fusion may predispose neighboring spinal motion segments to rapid deterioration. See, e.g., B.H. Cummins, J.T. Robertson, and S.S. Gill, *Surgical Experience With An Implanted Artificial Cervical Joint*, J. Neurosurg. 88:943-948, 1998. For example, removal of the intervertebral disc and subsequent fusion of the C3-C4 vertebrae may spur 35 deterioration of the C2-C3 and C4-C5 segments. A spinal fusion prevents the fused vertebrae from moving rotationally or translationally with respect to each

5 other, as natural disc tissue permits. That lack of mobility may increase the
stresses on adjacent spinal motion segments. Follow-up of patients undergoing a
successful fusion may reflect an incidence of neighboring segmental disease as
high as 20%, and indications are that 50% of fusion patients will continue to have
complaints of pain. Several conditions have been found at spinal segments
10 adjacent to a spinal fusion site, including disc degeneration, disc herniation,
instability, spinal stenosis, spondylosis and facet joint arthritis. Consequently,
many patients may require additional disc removal and/or fusion procedures as a
result of a spinal fusion. Alternatives to fusing a spinal motion segment therefore
clearly have inherent advantages.

15 Several different types of intervertebral disc arthroplasty devices have been
proposed for preventing collapse of the space between adjacent vertebrae, to
reduce pain and to maintain stability and range of rotational motion between the
vertebrae. For example, U.S. Patent No. 5,755,796 discloses a prosthesis for
implantation in the disc space between adjacent vertebrae. The prosthesis has two
20 elements, one being attached to the vertebra above the disc space, and the other
being attached to the vertebra below the disc space. The lower element includes a
hollow box frame having a spherical seat inside, and the upper element includes a
spherically-shaped head that fits into the spherical seat. U.S. Patent No. 5,556,431
discloses a three-piece intervertebral disc endoprosthesis, in which two plates, each
25 having a hollow in one side, are fixed to adjacent vertebrae so that the two hollows
face each other across the disc space. The third element is a core having an
outwardly rounded surface on each side that fits into the hollows in the vertebral
plates. Similarly, U.S. Patent No. 5,684,296 discloses a prosthesis having two L-
shaped members, each having curved sections between which a resilient disc body
30 is placed.

U.S. Patent Nos. 5,782,832 and 5,683,465 disclose implants having two
plate members anchored to adjacent vertebrae within the disc space. In U.S. Patent
No. 5,782,832, the upper plate member has a rounded underside and the lower
plate member has a hollowed top side to engage the underside of the upper plate
35 member and allow rotation. In U.S. Patent No. 5,683,465, the plate members have

5 a snap-fit ball and socket engagement allowing rotation. Other prosthetic intervertebral discs are also known. Some are composite components having metal and rubber or polymer inserts which are designed to replicate the characteristics and performance of the discs in separating and enabling movement of adjacent vertebrae with respect to each other. Other designs are more mechanical in nature, 10 including springs or other damping mechanisms also designed to approximate the behavior of a normal disc.

The normal movement of vertebrae with respect to one another involves variable rotation and translation. These components of the movement are dictated by the shape and size of the individual vertebrae including the relative positions of 15 the unconvertbral joints (in the cervical spine), the orientation of the facet joints and ligamentous constraints. In essence the axis of rotation for any two vertebrae is unique and during flexion or extension will shift, or translate.

The prior art describes disc prosthesis or joints that dictate a fixed axis of rotation that will not permit translation and will therefore prevent normal movement and tend to jam. The latter may lead to excessive stresses on the 20 prosthesis leading to wear or failure or be transferred to adjoining motion segments provoking pain and/or accelerated degeneration.

Further, many prior devices are relatively difficult to implant. Most are 25 designed to be attached via integral anchors to the vertebral surface facing the intervertebral disc space. To implant such a device, the adjacent vertebrae must be spread substantially further apart than their normal distance from each other, so that the prosthesis can be maneuvered between the vertebrae and the anchors can be inserted into their respective vertebrae. Such an operation presents additional risk of injury to the vertebrae themselves from misplacement or scratching by the 30 anchors, and to other tissues due to the spreading of the vertebrae beyond its normal span.

Therefore, there remains a need for an intervertebral joint prosthesis 35 allowing translational as well as rotational movement between implanted vertebrae, and which is easy to implant in a disc space. There is also a need for a method and instrumentation for implanting such an intervertebral joint prosthesis.

SUMMARY OF THE INVENTION

The present invention is directed to an intervertebral joint prosthesis having a ball component for engagement with a first vertebra and a trough component for engagement with a second vertebra adjacent to the first vertebra. The trough component includes a generally concave surface having a substantially flat portion. When the ball component and the trough component are engaged to their respective vertebrae, the ball component and the trough component engage each other in a ball-and-socket relationship permitting rotation and translation with respect to each other. Both the ball component and the trough component include a flange at one end of the component for engaging a vertebra.

The ball component includes a substantially spherically shaped convex portion which engages a substantially spherically shaped concave portion of the trough component, which concave portion also includes a flat portion. In one embodiment, the flanges of each component include holes through which bone screws can be fitted to attach the components to their respective vertebrae. The flanges may be configured to conform to the general shape of the human vertebrae.

By permitting the ball component to slide or translate in the trough component the present invention enables both the axis of rotation and the degree of translation of the joint to be dictated by the anatomical constraints of the motion segment within an acceptable range.

The invention also contemplates a tool for use in implanting an intervertebral joint prosthesis, having an elongated handle portion and a prosthesis-engaging portion having elements which hold the one or more parts of the intervertebral joint prosthesis. In one embodiment, the prosthesis-engaging portion of the tool includes a central flange and/or a surface configured so that the intervertebral prosthesis or its parts are maintained in a predetermined orientation or spatial relationship. Where the intervertebral joint prosthesis includes apertures for accommodating bone screws, the prosthesis-engaging portion of the tool preferably includes associated apertures for drilling holes for bone screws and/or for holding the prosthesis to the tool.

5 The present invention also encompasses methodology for implanting a two-part intervertebral joint prosthesis which includes placing the prosthesis parts in a predetermined spatial relationship, inserting the parts into a disc space between two adjacent vertebrae so that one of the prosthesis parts abuts one of the vertebrae and the other of the prosthesis parts abuts the other of the vertebrae and so that the 10 predetermined spatial relationship of the prosthesis parts is maintained, and fastening the parts to their respective vertebrae. Particular embodiments of the methodology include connecting the parts to an insertion tool in a predetermined relationship with each other, inserting the insertion tool into the body so that a portion of both parts of the prosthesis are in a disc space between adjacent 15 vertebrae, and fastening each part of the prosthesis to a respective vertebra. A preferred embodiment of the fastening step includes drilling holes in the vertebrae through apertures in the prosthesis parts and a connected insertion tool and threading screws through the apertures and into the bone.

20 The present invention provides an intervertebral joint prosthesis, and tools and methods for implantation, which allows a normal range of translation and rotation between the adjacent vertebrae to which the prosthesis has been fastened. The prosthesis is easy to implant via its flanges, obviating the need for distention 25 of the adjacent vertebrae to widen the disc space. The intervertebral joint prosthesis is also implanted with a predetermined orientation of the prosthesis or spatial relationship between its components, which reduces or eliminates the need for *in vivo* adjustment. The prosthesis of the present invention also has a low profile and a minimal number of parts. These and other advantages will be clear to one of ordinary skill in the art by reference to the drawings and to the detailed description herein.

5

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial sectional view, showing a side view of one embodiment of the prosthesis of the present invention implanted between adjacent vertebrae shown in cross-section.

10

FIG. 1a is a sectional view of the embodiment of the prosthesis illustrated in FIG. 1.

FIG. 2 is a front elevational view of an embodiment of the ball component of the prosthesis illustrated in FIG. 1.

15

FIG. 3 is a sectional view of the ball component illustrated in FIG. 2, taken along the line 3—3 and viewed in the direction of the arrows.

FIG. 4 is a sectional view of the ball component illustrated in FIG. 2, taken along the line 4—4 and viewed in the direction of the arrows.

20

FIG. 5 is a perspective view of an embodiment of the trough component of the prosthesis illustrated in FIG. 1.

FIG. 6 is a front elevational view of an embodiment of the trough component of the prosthesis illustrated in FIG. 1.

FIG. 7 is a sectional view of the trough component illustrated in FIG. 5, taken along the line 7—7 in FIG. 6 and viewed in the direction of the arrows.

25

FIG. 8 is a sectional view of the trough component illustrated in FIG. 5, taken along the line 8—8 in FIG. 6 and viewed in the direction of the arrows.

FIG. 9 is a side elevational view of an embodiment of the ball component illustrated in FIG. 2.

30

FIG. 10 is a side elevational view of an embodiment of the trough component illustrated in FIG. 5.

FIG. 11 is a sectional view of the ball component illustrated in FIG. 9, taken along the line 11—11 and viewed in the direction of the arrows.

FIG. 12 is a sectional view of the trough component illustrated in FIG. 10, taken along the line 12—12 and viewed in the direction of the arrows.

35

FIG. 13 is a perspective view of one embodiment of the insertion tool of the present invention.

5 FIG. 14a is a side view of the embodiment of the insertion tool illustrated in
FIG. 13.

FIG. 14b is a top view of the embodiment of the insertion tool illustrated in
FIG. 13, rotated 90 degrees around the longitudinal axis illustrated in FIG. 14a.

10 FIG. 15a is a side view of an alternate embodiment of the insertion tool of
the present invention.

FIG. 15b is a perspective view of one embodiment of the prosthesis of the
present invention engaged to the prosthesis engaging portion of the embodiment of
the insertion tool illustrated in FIG. 15a.

15 FIG. 16 is a perspective view of an embodiment of the prosthesis of the
present invention engaged with the insertion tool illustrated in FIG. 13.

FIG. 17 is a side elevational view of an embodiment of the prosthesis of the
present invention engaged with an embodiment of the prosthesis engaging surface
of the insertion tool illustrated in FIG. 13.

5

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

15 Referring generally to FIGS. 1-12, there is shown one embodiment of the intervertebral joint prosthesis 20 of the present invention. Prosthesis 20 includes a ball component 22 and a trough component 24 that are interengagable to form prosthesis 20. In an intervertebral disc space 28 between two adjacent vertebrae 26, 27, ball component 22 is fixed to one of the adjacent vertebrae (e.g. vertebra 26 in FIG. 1), and trough component 24 is fixed to the other adjacent vertebra (e.g. vertebra 27 in FIG. 1) so that the components are interengaged within at least a portion of intervertebral space 28.

20 Ball component 22 includes a generally convex surface 30 and in one embodiment an opposite substantially flat vertebra engaging surface 32. In a 25 particular embodiment, generally convex surface 30 is substantially spherical in shape. In a specific embodiment, a wedge surface 33 is provided at one end of vertebra engaging surface 32, which allows easier insertion of ball component 22 into the disc space and impedes migration of ball component 22. A flange 34 is provided at one end of ball component 22 for attaching ball component 22 to a 30 vertebra, and is preferably formed to have a low profile and bulk. In the embodiment in which ball component 22 includes wedge surface 33, flange 34 is at the opposite end of ball component 22 from wedge surface 33. Flange 34 includes a vertebra engaging surface 35.

35 In a particular embodiment of ball component 22, flange 34 includes one or more bone screw apertures 36, and in a specific embodiment, two bone screw

5 apertures 36 are provided in a symmetric relationship through flange 34. In that specific embodiment, one or more bone screws 37 (FIG. 4) are threaded into the vertebra through one or more apertures 36 to fix ball component 22 to the vertebra. In the illustrated embodiment, an aperture 38 (FIGS. 2 – 3) is also provided through flange 34 for a locking screw 39 (FIG. 1). After ball component 22 is 10 attached to the vertebrae using bone screw(s) 37, locking screw 39 is threaded into locking screw aperture 38 in flange 34, covering the heads of bone screw(s) 37 and preventing loosening of bone screw(s) 37 with respect to ball component 22. Additionally, the illustrated embodiment of ball component 22 includes 15 indentations 40 for gripping ball component 22 by an insertion tool, as will be described further hereinafter. Preferably, indentations 40 are located at the base of flange 34, where flange 34 meets substantially flat vertebra engaging surface 32.

Flange 34 may be angled with respect to vertebra engaging surface 32 of ball component 22. In a particularly preferred embodiment, as illustrated in FIG. 3, the internal angle A between vertebra engaging surface 35 and vertebra 20 engaging surface 32 is approximately 80 degrees. This angle has been found to provide a good fit with the anterior portion of the upper vertebra in a middle or lower cervical spinal motion segment, such as C4-C5. Ball component 22 can be constructed with a different angle between vertebra engaging surfaces 35 and 32 according to the vertebrae to be implanted and the needs of patients. For example, 25 for upper cervical spinal motion segments such as C2-C3, the internal angle between vertebra engaging surface 35 and vertebra engaging surface 32 may be somewhat more acute, in the range of 70 – 80 degrees. Flange 34 may also be slightly curved from side to side, as illustrated in FIG. 4. Such curvature is particularly useful for anterior placement of prosthesis 20, as it approximates the 30 lateral curvature of the anterior surface of the human vertebra.

Trough component 24, in the embodiment illustrated, is similar in many respects to ball component 22. Trough component 24 includes a generally concave surface 50, which generally concave surface 50 includes a substantially flat portion 52 (FIGS. 5 – 7). Opposite generally concave surface 50 is a vertebra engaging 35 surface 54, which, in the illustrated embodiment, includes a wedge surface 55.

5 similar to wedge surface 33 of ball component 22. Trough component 24 also includes a flange 56 and a flange vertebrae engaging surface 57 which are similar to flange 34 and flange vertebra engaging surface 35 of ball component 22.

As with a particular embodiment of ball component 22, the illustrated embodiment of flange 56 of trough component 24 includes at least one aperture 58 10 and preferably two symmetric apertures 58, each of which can accommodate a bone screw 59 (FIG. 8). In that embodiment, flange 56 may also include a lock screw aperture 60 and lock screw 61, as described with respect to ball component 22. Additionally, trough component 24 in one embodiment includes indentations 15 62, which are similar in location and structure to indentations 40 of ball component 22. Flange 56 of trough component 24, in a preferred embodiment, is also angled with respect to vertebra engaging surface 54. In the illustrated embodiment, the internal angle B between flange vertebra engaging surface 57 and vertebra 20 engaging surface 54 is approximately 95 degrees, which provides a good fit with the anterior portion of a lower vertebra of a middle or lower cervical spinal motion segment. As noted with respect to ball component 22, trough component 24 may be manufactured with a different angle between surfaces 57 and 54 according to the needs of the patient or other factors. For example, for upper cervical spinal motion segments, the angle between surfaces 57 and 54 may be between 90 and 100 degrees.

25 Referring now to FIGS. 5, 7 and 10, the generally concave surface 50 of trough component 24 is illustrated according to one embodiment of the present invention. Generally concave surface 50, in this embodiment, includes a substantially flat (in that it is cylindrical rather than spherical) surface 52 that is approximately centrally located on generally concave surface 50. In a specific 30 embodiment, generally concave surface 50 includes substantially spherical surfaces 64 on both sides of substantially flat surface 52. Substantially flat surface 52 may be of any desired geometrical configuration, though in a currently preferred embodiment, substantially flat surface 52 is in the shape of a rectangle, analogous to a slot in generally concave surface 50, and is approximately parallel to flange 35 56. In a particular preferred embodiment of ball component 22 and trough

5 component 24, the radius of generally convex surface 30 and of the spherical portion of generally concave surface 50 is approximately the same.

In use, ball component 22 and trough component 24 are attached to adjacent vertebrae so that a portion of components 22, 24 are within the disc space and engage each other to provide a ball-and-socket arrangement which permits 10 rotation and translation of the components, and thereby the vertebrae to which they are fixed with respect to each other. To accomplish that, when prosthesis 20 is implanted generally convex surface 30 of ball component 22 engages generally concave surface 50 of trough component 24. When engaged with generally concave surface 50, generally convex surface 30 can rotate in any direction. When 15 generally convex surface 30 is in contact with substantially flat portion 52 of generally concave surface 50, generally convex surface 30 can move along substantially flat portion 52 in translation, as well as rotate with respect to generally concave surface 50. In a specific embodiment of prosthesis 20, ball component 22 is an "upper" component and is fixed to the vertebra immediately 20 above or superior to the disc space (i.e. the vertebra closer to the head). In that embodiment, trough component 24 is attached to the lower or inferior vertebra (i.e. the vertebra closer to the coccyx). Thus, with ball component 22 attached to one vertebra and trough component 24 attached to an adjacent vertebra so that generally convex surface 30 and generally concave surface 50 are engaged, 25 prosthesis 20 permits the adjacent vertebrae to rotate and translate with respect to each other, providing a normal range of intervertebral joint motion.

The present invention also comprehends an insertion tool 70 for use in implanting joint prosthesis 20. As illustrated in FIGS 13-17, insertion tool 70 in one embodiment includes an elongated handle portion 72 integral with or attached 30 to an extension portion 74. A prosthesis-engaging portion 76 is attached at the end of extension portion 74. Prosthesis-engaging portion 76 includes prosthesis-engaging surface 78. Prosthesis-engaging surface 78, in the illustrated embodiment, includes a central separator flange 79. The illustrated embodiment of prosthesis-engaging portion 76 also includes a set of apertures 80. This 35 embodiment of insertion tool 70 is intended for use with the embodiment of ball

5 component 22 and trough component 24 having bone screw aperture(s) 36 and 58, respectively, and apertures 80 of prosthesis-engaging portion 76 are configured so as to communicate with aperture(s) 36 of ball component 22 and aperture(s) 58 of trough component 24. In that embodiment, apertures 80 are sized slightly larger than the head(s) of bone screw(s) 37, so that screw(s) 37 may be inserted through 10 apertures 80 to fix components 22 and 24 of prosthesis 20 to their respective vertebrae without also fixing tool 70 thereto.

Prosthesis-engaging portion 76 of insertion tool 70 is also capable of retaining prosthesis 20 in engagement with prosthesis-engaging portion 76. The illustrated embodiment of prosthesis-engaging portion 76 also includes a pair of 15 clips 82 on both sides of prosthesis-engaging portion 76. Clips 82 are designed to hold the embodiments of ball component 22 and trough component 24 that include indentations 40 and 62, respectively. Each clip 82 is attached to prosthesis engaging portion 76, and includes two clip fingers 84 each having a thickened portion 86 for insertion into indentations 40 of ball component 22 and indentations 20 62 of trough component 24. In an alternative embodiment of insertion tool 70 (FIGS. 15a – 15b), prosthesis-engaging portion 76 is provided with apertures 80, and a pair of cam screws 90 which extend through one aperture 80 on each side of separator flange 79. Ball component 22 and trough component 24, in the embodiment in which they include bone screw apertures 36 and 58, respectively, 25 are engaged to prosthesis engaging surface 78 so that apertures 36 and 58 communicate with apertures 80 of prosthesis engaging portion 76. Cam screws 90 are then inserted into one of apertures 36 and one of apertures 58 to lock ball component 22 and trough component 24 to prosthesis engagement surface 76.

As illustrated in Figure 14a – 17, a particular embodiment of prosthesis-engaging portion 76 is configured to maintain ball component 22 and trough component 24 in a predetermined spatial relationship or neutral position so as to insure correct alignment and positioning of the components with respect to each other and with respect to disc space and vertebrae into which they are to be implanted. Separator flange 79 of prosthesis engaging portion 76 is configured to 30 fit between and to insure the proper spacing between ball component 22 and trough 35 component 24.

5 component 24. Prosthesis-engaging surface 78 is angled so that, in cooperation with separator flange 79, prosthesis-engaging portion 76 holds ball component 22 and trough component 24 in a precise predetermined spatial relationship with each other. For example, in the embodiments described above in which vertebra engaging surfaces 32 and 35 of ball component 22 have an internal angle of 80
10 degrees, prosthesis engaging surface 78 will include a portion forming an internal angle of approximately 80 degrees with separator flange 79. Similarly, in the embodiment of trough component 24 in which vertebra engaging surfaces 54 and 57 have an internal angle of approximately 95 degrees, prosthesis engaging surface 78 will include a portion which forms an internal angle of approximately 95
15 degrees with separator flange 79. Ball component 22 and trough component 24 are thereby held for implantation together such that vertebra engaging surface 32 of ball component 22 and vertebra engaging surface 54 of trough component 24 are approximately parallel, and such that convex surface 30 is engaged with concave surface 50.

20 Insertion tool 70 has been described above primarily with respect to the embodiments of prosthesis 20 described herein. Nonetheless, one of ordinary skill in the art will appreciate that insertion tool 70 may be useful with other prostheses that must be held in a particular predetermined orientation, or that have parts that must be retained in a particular spatial relationship.

25 After an intervertebral disc is resected and/or the disc space is prepared, the intervertebral joint prosthesis 20 of the present invention may be implanted. Ball component 22 and trough component 24 of joint prosthesis 20 are placed in a predetermined relationship with each other, preferably by engagement to insertion tool 70 of the present invention or an equivalent tool. Components 22 and 24, held
30 in a predetermined spatial relationship, are then inserted into the body so that vertebra engaging surfaces 32 and 54 are within the disc space. In the embodiments of components 22 and 24 that include a wedge surface 33 and 55, respectively, wedge surfaces 33 and 55 enable easier implantation of prosthesis 20 by forcing the adjacent vertebrae apart slightly, if necessary, as components 22 and
35 24 are advanced into the disc space. Once components 22 and 24 are inserted into

5 the disc space, wedge surfaces 33 and 55 grip their respective vertebrae to impede or prevent migration of prosthesis 20.

When prosthesis 20 is in place between the vertebrae, components 22 and 24 are attached to the vertebrae, in one embodiment via flanges 34 and 56. In the embodiment of the present invention in which flanges 34 and 56 include bone

10 screw apertures 36 and 58, respectively, attachment of the components 22 and 24 to the vertebrae may be accomplished by drilling through apertures 36 and 58 into the vertebrae. The drill is then removed and bone screws are threaded into the 15 vertebrae through apertures 36 and 58, thereby fixing components 22 and 24 to their respective vertebrae. When all holes have been drilled and all screws 37 have been threaded into the vertebrae, insertion tool 70 is removed (if one has been used), locking screws may be threaded into apertures 38 and 60 (if present in components 22 and 24), and the operation is concluded.

A specific embodiment of the method of implanting the joint prosthesis 20 includes use of an embodiment of insertion tool 70. In the method using the

20 embodiment of insertion tool 70 having four apertures 80 and a clip 82 on both sides of prosthesis engaging portion 76, components 22 and 24 of joint prosthesis 20 are engaged to insertion tool 70 in a predetermined spatial relationship as described above. Insertion tool 70 is inserted into the body so that joint prosthesis 20 is in the disc space between adjacent vertebrae. A drill (and a drill sleeve, if necessary) is inserted through an aperture 80 in prosthesis engaging portion 76 and through an aperture 36 or 58 of component 22 or component 24 communicating with the aperture 80, and a hole is drilled in the underlying vertebra. The drilling procedure is repeated for each of the apertures 80 in prosthesis engaging portion 76 which communicate with an aperture 36 or 58 in ball component 22 or trough component 24, respectively. Screws 37 are threaded into the vertebrae through apertures 80 and apertures 36 and 58, fixing components 22 and 24 to their respective vertebrae. Apertures 80 of prosthesis engaging portion 76 are sized slightly larger than the heads of the bone screws 37 used to attach components 22 and 24 to their respective vertebrae. When all of the holes have been drilled and 35 all of the screws have been threaded into the bone, clips 82 are disengaged from

5 components 22 and 24 and insertion tool 70 is removed. Similarly, in the embodiment of insertion tool 70 illustrated in FIGS. 15a – 15b having cam screws 90, components 22 and 24 are attached to prosthesis-engaging portion 76 by locking cam screws 90 into one each of apertures 36 and 58. Holes are drilled through apertures 80 and apertures 36 and 58 not occupied by cam screws 90.

10 After such holes are drilled, screws are threaded into such vertebra holes. The cam screws are then unlocked, the insertion tool 70 is removed and the remaining holes are drilled through apertures 36 and 58 in components 22 and 24. Bone screws 37 are threaded into the vertebrae through components 22 and 24 to complete the fixation of components 22 and 24 to their respective vertebrae.

15 The devices and methods of the present invention are currently believed to be most useful in repairing vertebral joints in the cervical region. Nevertheless, it is believed that the devices and methods of the present invention could also be useful in repairing other spinal motion segments as well.

In the embodiments of ball component 22 and trough component 24 which include a locking screw aperture 38 and 60, respectively, fixation of joint prosthesis 20 is completed by threading a locking screw (not shown) into apertures 38 and 60. When components 22 and 24 of joint prosthesis 20 are satisfactorily fixed, the operation may be concluded.

The attachment of components 22 and 24 to vertebrae has been primarily described through use of bone screws fixing the components to the vertebrae. It is understood that alternative attachment structures or methods may be used, such as by stapling or by applying adhesive to vertebra engaging surfaces 32, 35, 54 and/or 57; so long as components 22 and 24 are firmly fixed to their respective vertebrae so as to withstand the stresses inherent in continual rotational and translational movements. Further, joint prosthesis 20, as well as the bone screws or other structures used to implant them within the body, are preferably made of biocompatible materials such as stainless steel, titanium, or other known biocompatible materials or their equivalents. Insertion tool 70 can be made of any appropriate material, although stainless steel is preferred.

5 While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

5 What is claimed is:

1. An intervertebral joint prosthesis, comprising:
 - a ball component for engagement with a first vertebra, said ball component including a generally convex surface, and a flange at one end of said ball component for engaging the first vertebra; and
 - 10 a trough component for engagement with a second vertebra adjacent to the first vertebra, said trough component including a generally concave surface with a substantially flat portion, and a flange at one end of said trough component for engaging the second vertebra;
 - wherein said generally convex surface and said generally concave surface are engaged together when said ball component and said trough component are engaged to the first vertebra and the second vertebra, respectively, and the engagement of said generally convex surface and said generally concave surface permits rotation of said ball component and said trough component with respect to each other, and the engagement of said generally convex surface and said
 - 15 substantially flat portion of said generally concave surface permits translation of said ball component and said trough component with respect to each other.
2. The intervertebral joint prosthesis of claim 1, wherein said generally convex surface is substantially spherical.
- 25 3. The intervertebral joint prosthesis of claim 2, wherein said generally concave surface includes a substantially spherical portion adjoining said substantially flat portion.

5 4. The intervertebral joint prosthesis of claim 3, wherein said generally concave surface includes two substantially spherical portions and said substantially flat portion is approximately centrally located with respect to said substantially spherical portions.

10 5. The intervertebral joint prosthesis of claim 4, wherein said substantially flat portion is substantially rectangular.

6. The intervertebral joint prosthesis of claim 5, wherein said substantially spherical portions of said generally concave surface and said substantially spherical portion of said generally convex surface have about the same radius.

15 7. The intervertebral joint prosthesis of claim 4, wherein said substantially flat portion is substantially parallel to said flange of said trough component.

20 8. The intervertebral joint prosthesis of claim 1, wherein said flange of said ball component and said flange of said trough component each include at least one aperture for receiving a bone screw.

25 9. The intervertebral joint prosthesis of claim 8, wherein said flange of said ball component and said flange of said trough component each include two apertures for receiving bone screws, said apertures having non-planar longitudinal axes.

30 10. The intervertebral joint prosthesis of claim 8, wherein said ball component and said trough component each include an aperture for receiving a locking screw adjacent to said aperture for receiving a bone screw.

35 11. The intervertebral joint prosthesis of claim 1, wherein said flange of said ball component and said flange of said trough component both include a curved portion.

5 12. The intervertebral joint prosthesis of claim 1, wherein said ball component includes a surface opposite said generally convex surface for engaging the first vertebra, and said flange of said ball component forms an internal angle of about 80 degrees with said surface for engaging the first vertebra.

10 13. The intervertebral joint prosthesis of claim 1, wherein said trough component includes a surface opposite said generally concave surface for engaging the second vertebra, and said flange of said trough component forms an internal angle of about 95 degrees with said surface for engaging the second vertebra.

15 14. A tool for use in implanting an intervertebral joint prosthesis, comprising:
an elongated handle portion;
a prosthesis engaging portion connected to said handle portion for holding the prosthesis; and
means connected to said prosthesis engaging portion for retaining the prosthesis in engagement with said prosthesis engaging portion.

20 15. The tool of claim 14, wherein said prosthesis engaging portion further includes a plurality of apertures.

25 16. The tool of claim 15, wherein said means for retaining the prosthesis includes a plurality of clips.

17. The tool of claim 15, wherein said means for retaining the prosthesis includes a plurality of cam screws.

30 18. The tool of claim 15, wherein said prosthesis engaging portion includes a prosthesis engaging surface for maintaining the prosthesis in a predetermined orientation.

35 19. The tool of claim 18, wherein said prosthesis engaging surface includes at least one portion configured at an oblique angle to said handle portion.

5

20. The tool of claim 18, wherein said prosthesis engaging surface includes a flange.
- 10 21. The tool of claim 20, wherein said prosthesis engaging surface includes at least one surface portion abutting said flange configured at an oblique angle to said handle portion.
- 15 22. A tool for use in implanting an intervertebral joint prosthesis having a part to be attached to an upper vertebra and a part to be fixed to a lower vertebra, said parts each including at least one aperture, said tool comprising:
 - 15 an elongated handle portion;
 - 15 a prosthesis engaging portion connected to said handle portion, said prosthesis engaging portion having a plurality of apertures which communicate with said apertures of said prosthesis parts when said prosthesis is engaged to said prosthesis engaging portion;
 - 20 means connected to said prosthesis engaging portion for retaining the prosthesis parts in engagement with said prosthesis engaging portion; and
 - 20 means connected to said prosthesis engaging portion for maintaining the prosthesis parts in a predetermined spatial relationship.
23. The tool of claim 22, wherein said means for retaining the prosthesis parts 25 includes a plurality of clip members.
24. The tool of claim 23, wherein said clip members are adapted to simultaneously engage both parts of the intervertebral prosthesis.
- 30 25. The tool of claim 22, wherein said means for retaining the prosthesis parts includes a plurality of cam screws, said cam screws being adapted to extend through said apertures in said prosthesis engaging portion and into the apertures in the prosthesis parts to hold the prosthesis parts.

5 26. The tool of claim 22, wherein said means for maintaining the prosthesis parts includes a prosthesis engaging surface on said prosthesis engaging portion.

27. The tool of claim 26, wherein said prosthesis engaging surface includes at least one portion configured at an oblique angle to said handle portion.

10 28. The tool of claim 26, wherein said prosthesis engaging surface includes a flange.

29. The tool of claim 28, wherein said flange is approximately centrally located 15 on said prosthesis engaging surface.

30. The tool of claim 28, wherein said prosthesis engaging surface includes at least one surface portion abutting said flange configured at an oblique angle to said handle portion.

20 31. A method of implanting a two-part intervertebral joint prosthesis in a body, comprising the steps of:

placing the prosthesis parts in a predetermined spatial relationship;

inserting the prosthesis parts into a disc space between two adjacent

25 vertebrae so that one of the prosthesis parts abuts one of the vertebrae and the other of the prosthesis parts abuts the other of the vertebrae and so that the predetermined spatial relationship of the prosthesis parts is maintained; and

fastening the prosthesis parts to their respective vertebrae.

30 32. The method of claim 31, wherein said placing step further includes the step of engaging the prosthesis parts to an insertion tool.

33. The method of claim 32, wherein said engaging step further includes the step of holding the prosthesis parts to the insertion tool by a plurality of clips.

5 34. The method of claim 32, wherein said engaging step further includes the
step of holding the prosthesis parts to the insertion tool by a plurality of cam
screws.

10 35. The method of claim 31, wherein said inserting step further includes
inserting the prosthesis parts through an anterior approach to the vertebrae.

36. The method of claim 31, wherein said fastening step includes fastening the
prosthesis parts to their respective vertebrae by a plurality of bone screws.

15 37. The method of claim 31, wherein said fastening step includes fastening the
prosthesis parts to their respective vertebrae by an adhesive.

38. A method of implanting a two-part intervertebral joint prosthesis in a body,
comprising the steps of:
20 providing a two-part intervertebral joint prosthesis, the prosthesis parts
each having a flange with at least one aperture therethrough;
placing the prosthesis parts in a predetermined spatial relationship;
inserting the prosthesis parts into a disc space between two adjacent
25 vertebrae so that the flange of one of the prosthesis parts abuts one of the vertebrae
and the flange of the other of the prosthesis parts abuts the other of the vertebrae
and so that the predetermined spatial relationship of the prosthesis parts is
maintained; and
fastening the flanges of the prosthesis parts to their respective vertebrae.

30 39. The method of claim 38, further including the step of providing an insertion
tool having a plurality of apertures which communicate with the apertures of the
flanges of the prosthesis parts, and wherein said placing step further includes the
step of engaging the prosthesis parts to the insertion tool.

5 40. The method of claim 39, wherein said engaging step further includes the
step of retaining the prosthesis parts to the insertion tool by a plurality of clips.

10 41. The method of claim 39, wherein said engaging step further includes the
step of retaining the prosthesis parts to the insertion tool by a plurality of cam
screws.

15 42. The method of claim 38, wherein said inserting step further includes
inserting the prosthesis parts anteriorly.

20 43. The method of claim 38, wherein said fastening step further includes the
steps of:
 placing a drill through an aperture of the insertion tool and the associated
 aperture of the prosthesis part;
 drilling a hole in the vertebra; and
 threading a bone screw into the hole in the vertebra through the aperture of
 the insertion tool and the associated aperture of the prosthesis part.

25 44. The method of claim 43, wherein said drill placing, drilling and threading
steps are repeated for each aperture in each prosthesis part flange.

30 45. The method of claim 44, further including the step of threading a locking
screw into each of the prosthesis parts so as to cover a portion of the head of each
bone screw.

35 46. The method of claim 38, wherein said fastening step includes fastening the
prosthesis parts to their respective vertebrae by an adhesive.

47. An intervertebral joint prosthesis system, comprising:
 a ball component having a generally convex surface and a flange adapted to
 be fastened to a first of two adjacent vertebrae;

5 a trough component having a generally concave surface for engaging said generally convex surface, said trough component being adapted to be fastened to a second of two adjacent vertebrae; and

10 an insertion tool adapted to hold said ball component and said trough component and to maintain said components in a predetermined spatial relationship.

48. The system of claim 47, wherein said flange of said ball component and said flange of said trough component each include at least one aperture therethrough.

15

49. The system of claim 48, further including a plurality of bone screws for fastening said ball component and said trough component to their respective vertebrae through said apertures.

20 50. The system of claim 48, wherein said insertion tool includes a plurality of apertures which communicate with said apertures through said flanges of said ball component and said trough component when said insertion tool holds said components.

25 51. The system of claim 50, wherein said insertion tool includes a prosthesis engaging surface configured to maintain said components in said predetermined spatial relationship when said insertion tool holds said components.

30 52. The system of claim 51, wherein said insertion tool includes a plurality of clip members for holding said components.

53. The system of claim 51, wherein said insertion tool includes a plurality of cam screws for holding said components.

5 54. The system of claim 47, wherein said generally concave surface includes a substantially flat portion.

55. The system of claim 54, wherein said generally concave surface includes at least one substantially spherical portion.

10

56. The system of claim 55, wherein said generally convex surface is substantially spherical.

57. The system of claim 56, wherein said at least one substantially spherical portion of said generally concave surface and said substantially spherical generally convex surface have about the same radius.

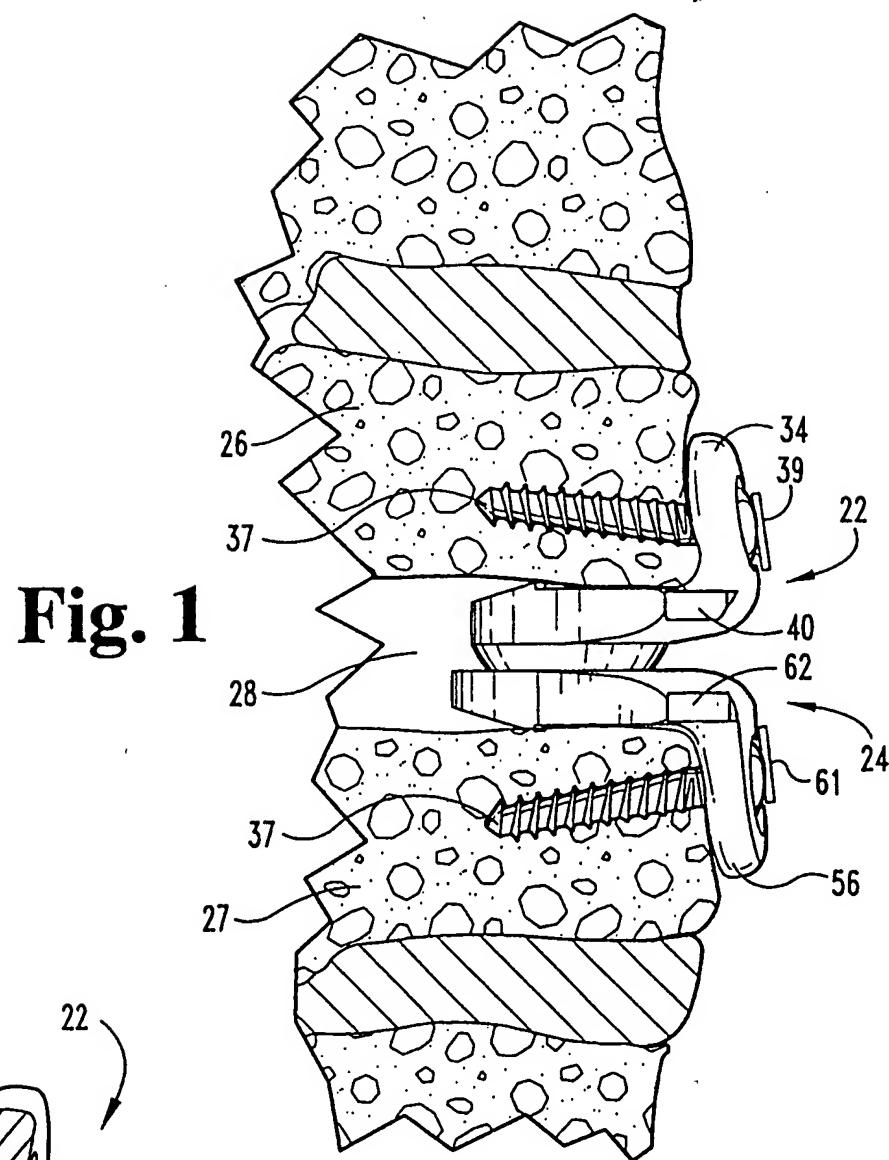


Fig. 1

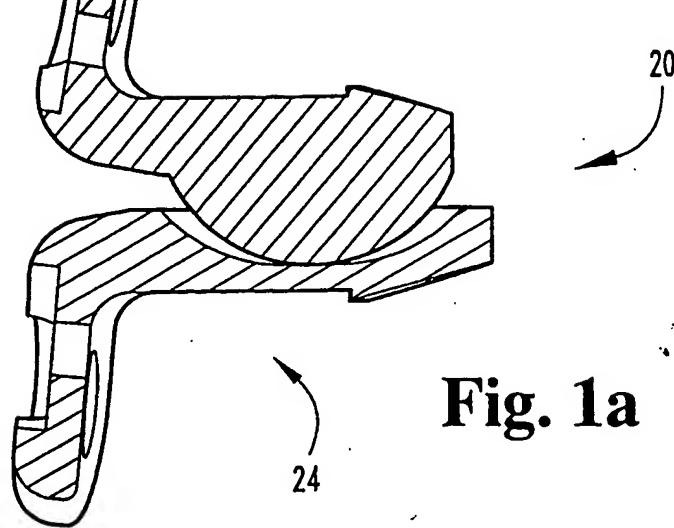


Fig. 1a

24

Fig. 3

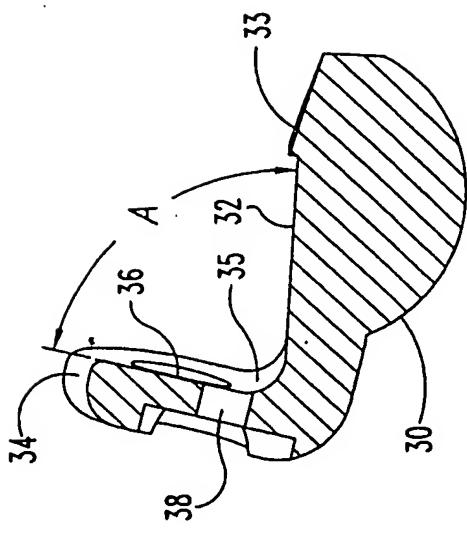


Fig. 2

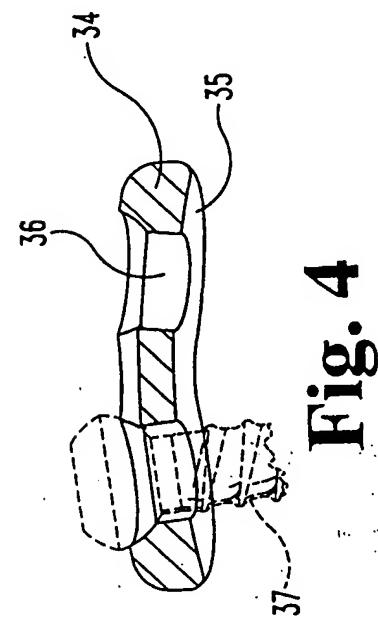
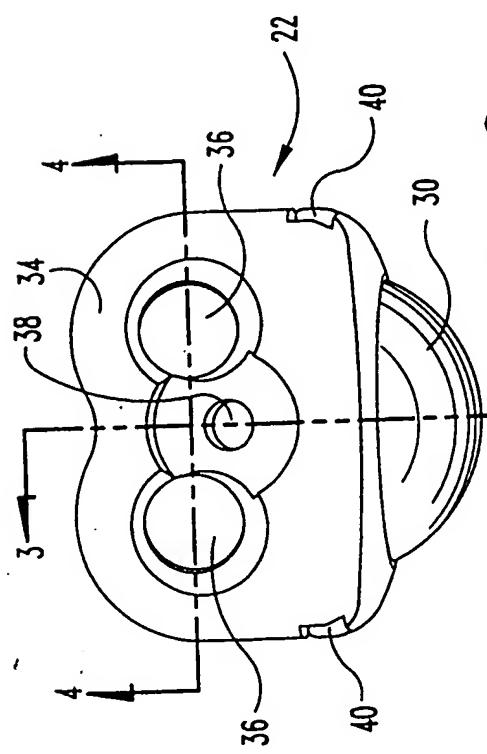
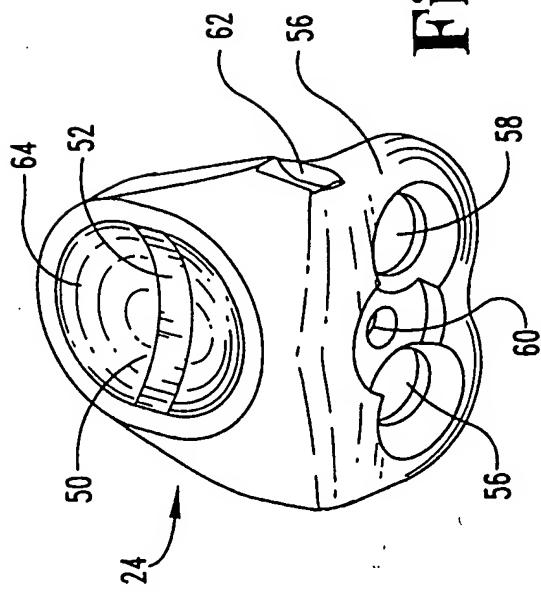


Fig. 5



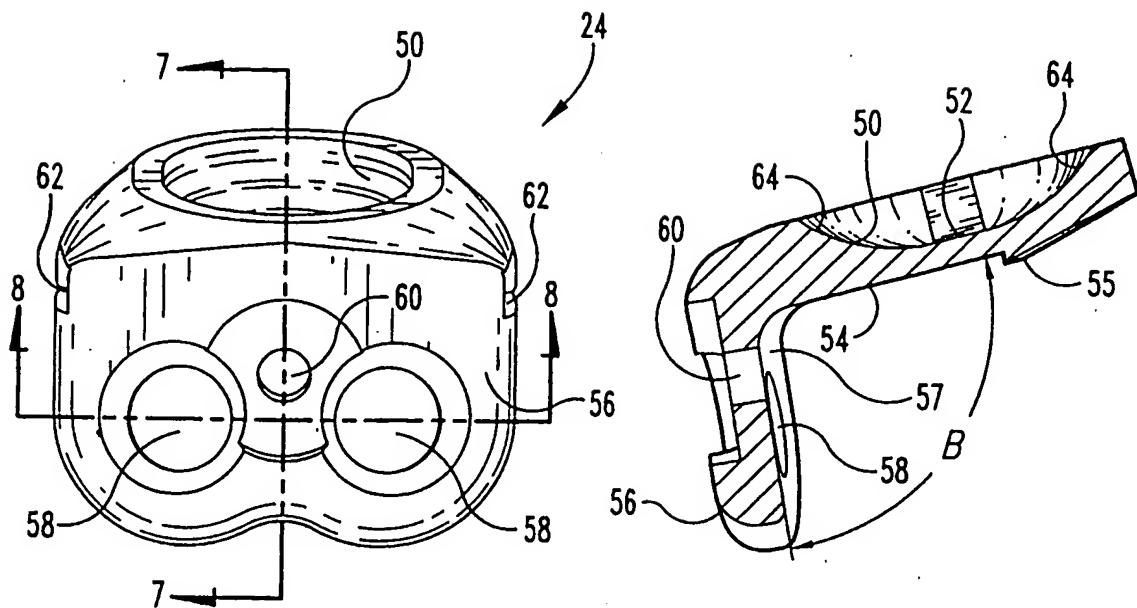


Fig. 6

Fig. 7

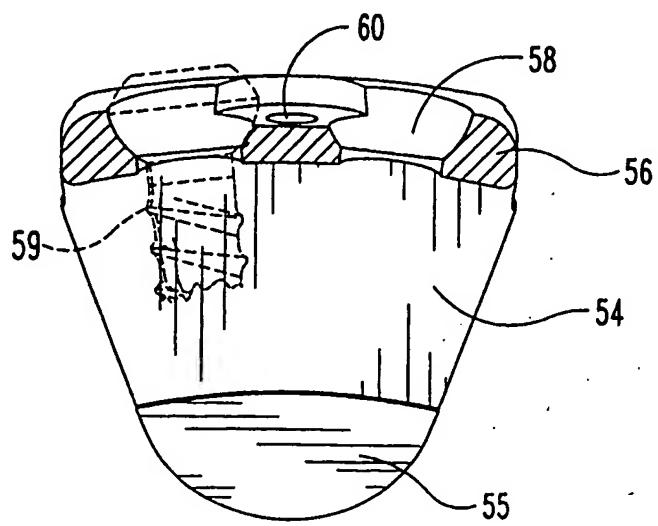


Fig. 8

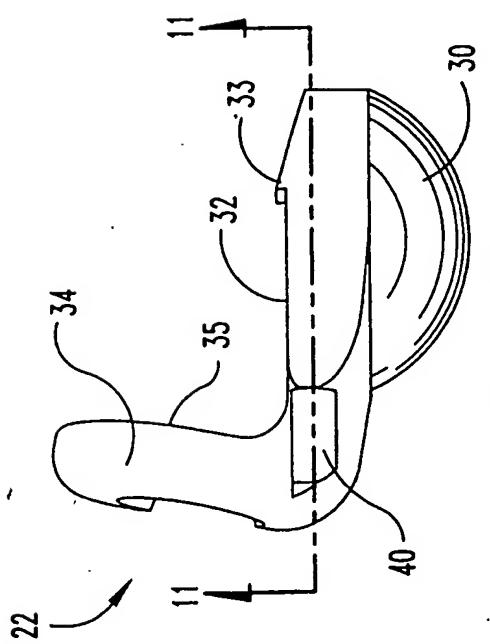


Fig. 9

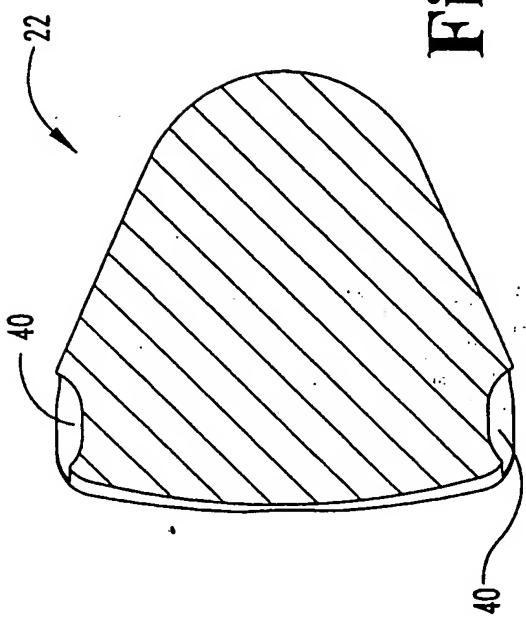


Fig. 11

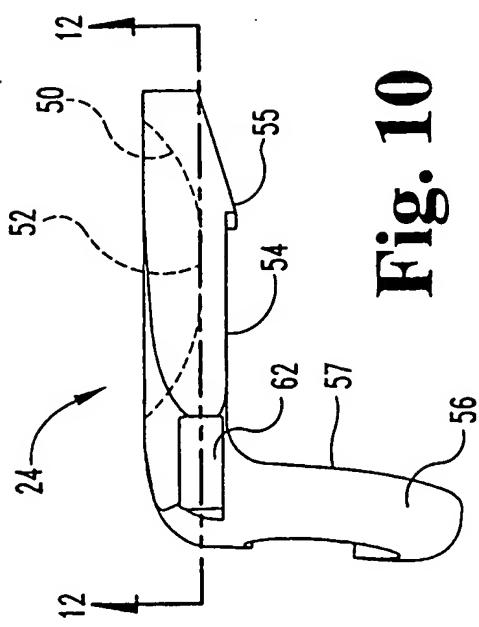


Fig. 10

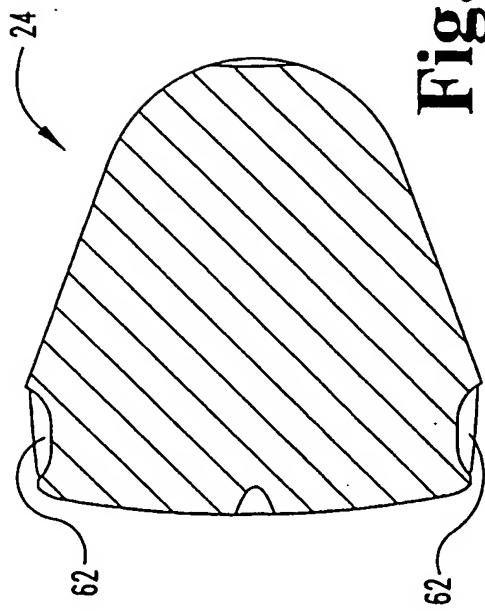
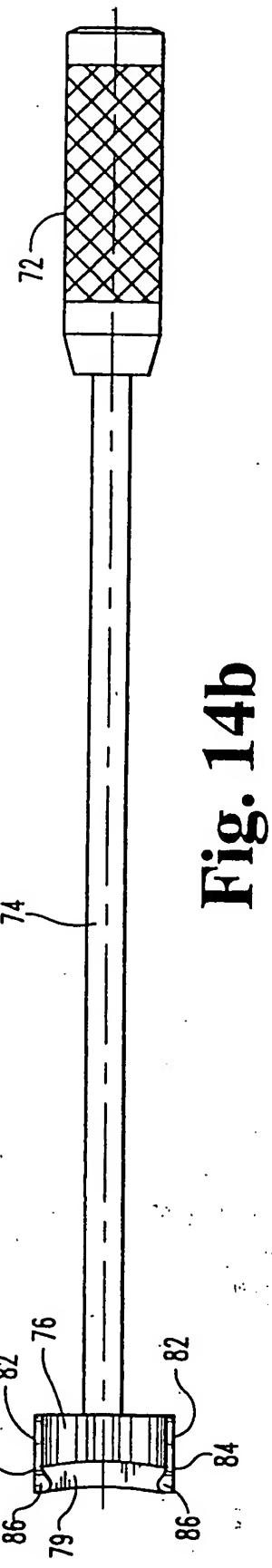
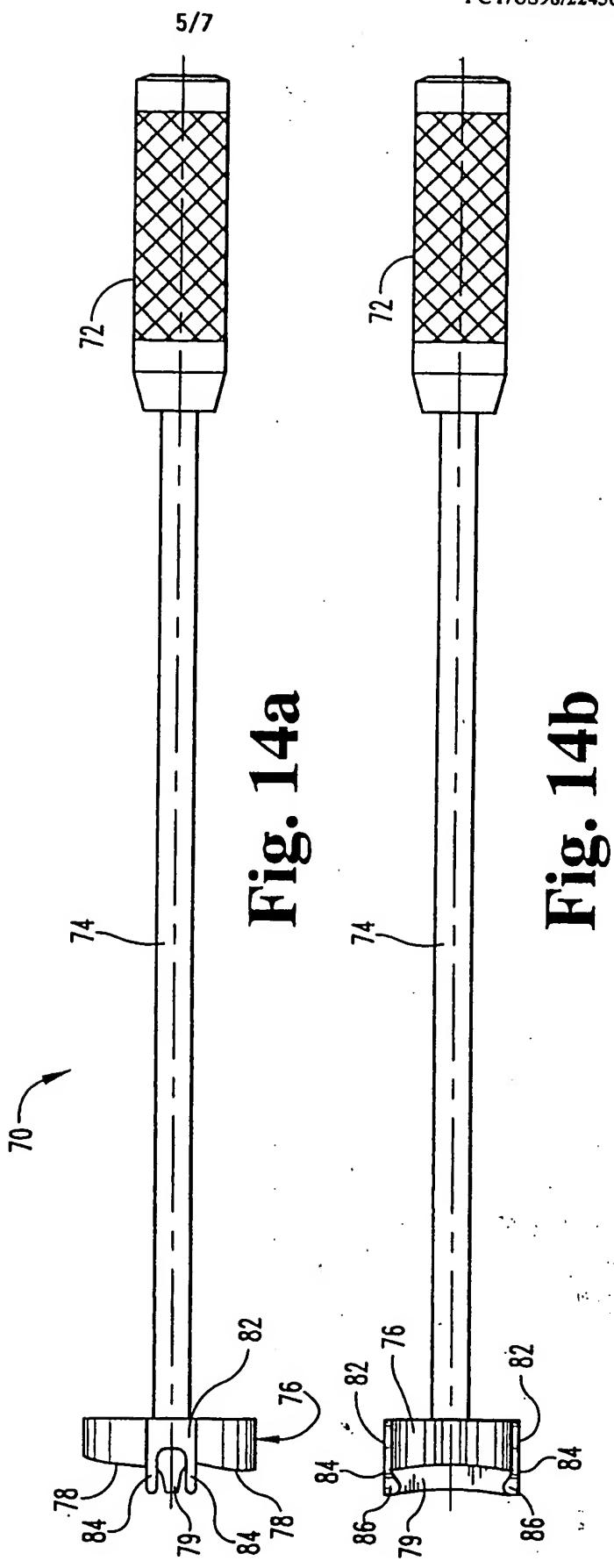
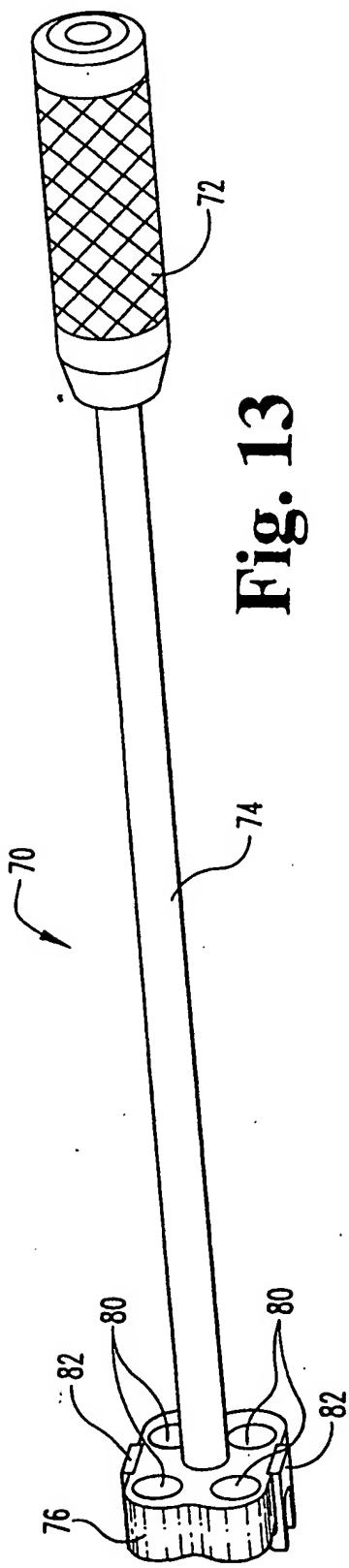


Fig. 12



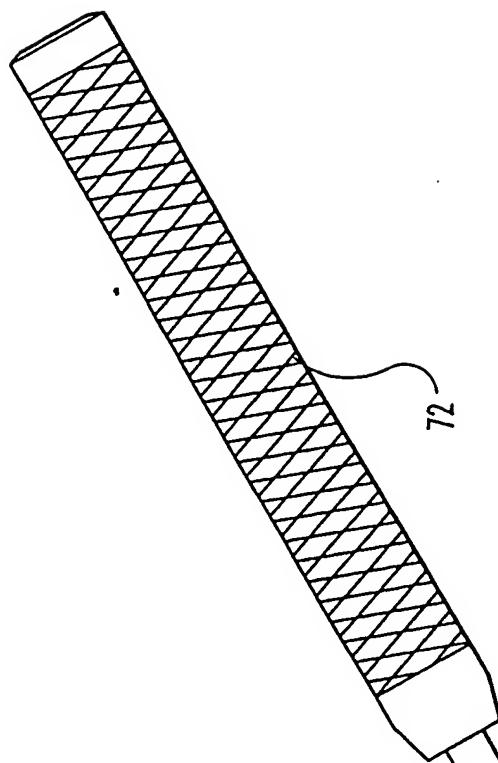


Fig. 15a

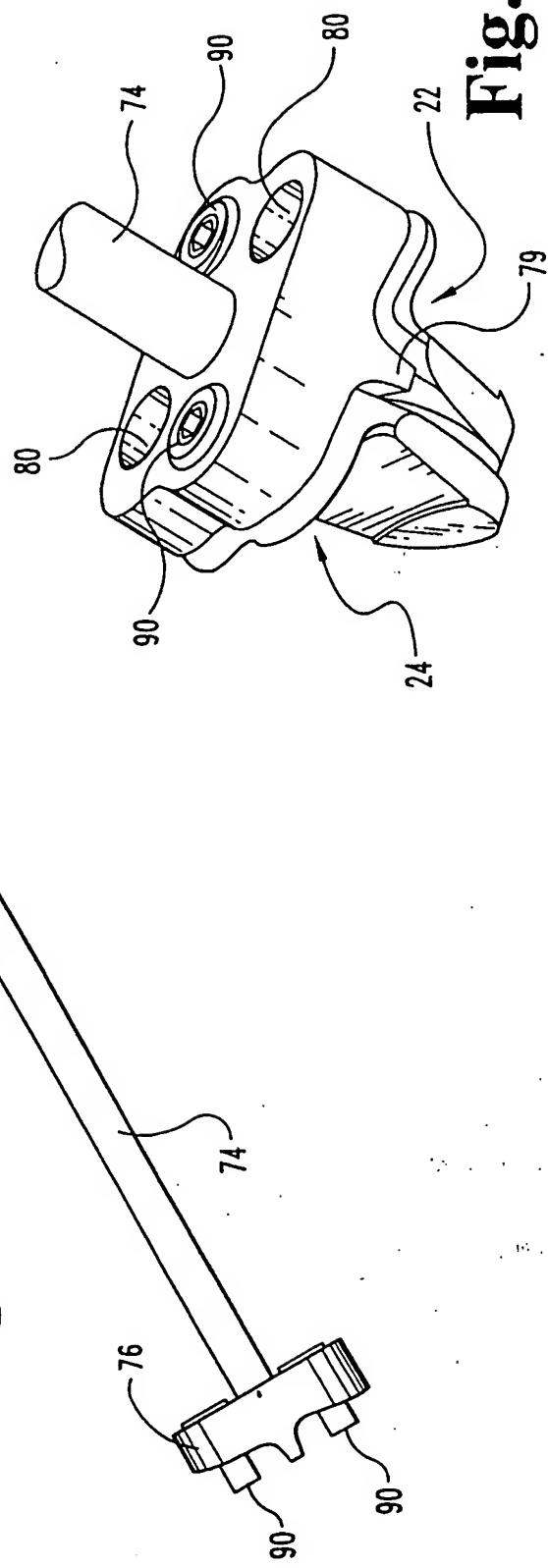


Fig. 15b

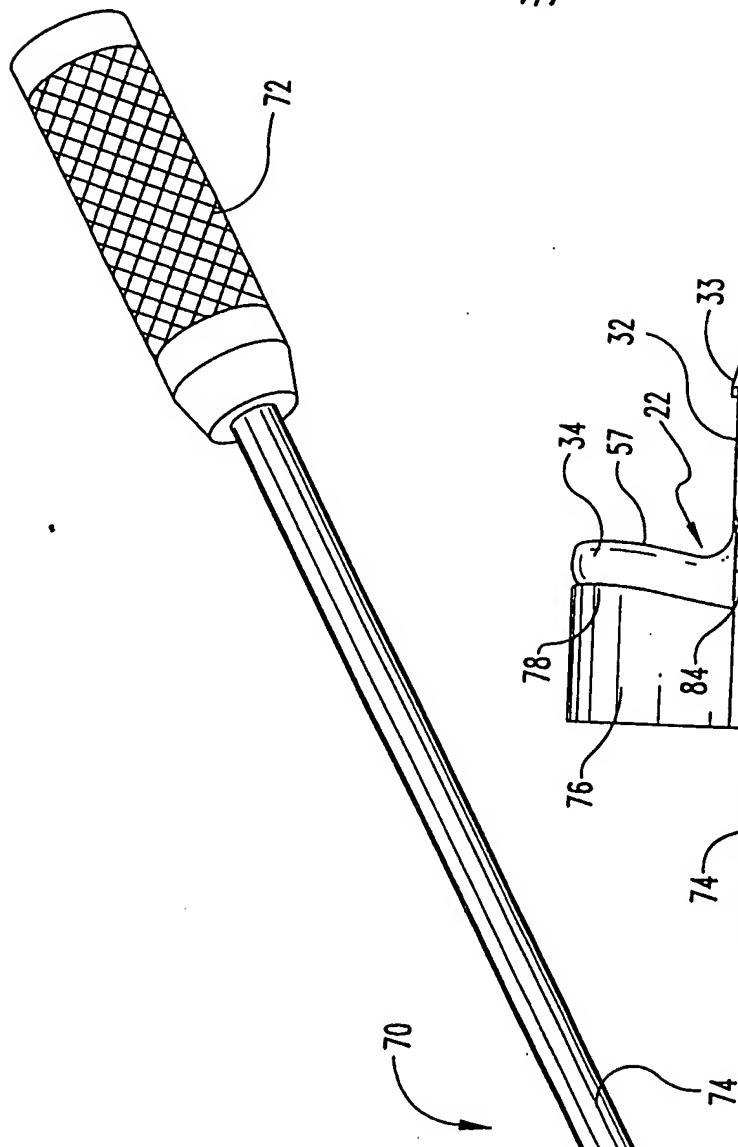


Fig. 16

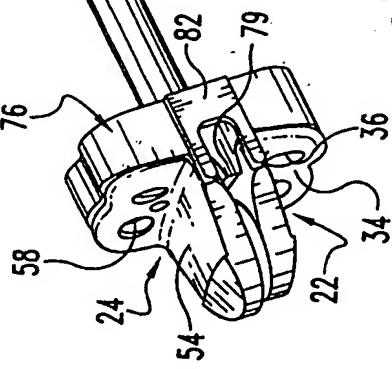


Fig. 17

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/22436

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91 13598 A (J.B.S.) 19 September 1991 (1991-09-19) the whole document	14
Y		47-49
A		1,2,6, 18,22, 24,26, 51,56,57
X	FR 2 737 656 A (JBS) 14 February 1997 (1997-02-14) the whole document	14
A		18,22, 24,26, 47,51
Y	EP 0 699 426 A (MEDINOV) 6 March 1996 (1996-03-06) claims; figures 14,19	1,2,8,9, 11,47-49
A		6,56,57
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

13 July 1999

20/07/1999

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Klein, C

INTERNATIONAL SEARCH REPORT

Int. Application No

PCT/US 98/22436

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 593 445 A (WAITS) 14 January 1997 (1997-01-14) abstract; figures 2-9D ---	1,2,8,9, 11
A	WO 93 10725 A (CUSTOMFLEX LIMITED) 10 June 1993 (1993-06-10) the whole document ---	1
A	FR 2 718 635 A (AXCYL MEDICAL) 20 October 1995 (1995-10-20) the whole document ---	1,2,6,8, 47-49, 56,57
A	US 5 782 927 A (KLAWITTER) 21 July 1998 (1998-07-21) column 8, line 39 - line 51; figure 4 ---	3-5,54, 55
A	US 3 795 922 A (HERBERT) 12 March 1974 (1974-03-12) column 7, line 37 - line 40; figures 1,2,4 ---	4,5
A	US 3 426 364 A (LUMB) 11 February 1969 (1969-02-11) column 3, line 49; figures 1,5,7 ---	8
A	US 5 425 773 A (BOYD) 20 June 1995 (1995-06-20) ---	
A	US 5 755 796 A (IBO) 26 May 1998 (1998-05-26) cited in the application -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/22436

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 31-46 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/US 98/22436

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 9113598	A 19-09-1991	FR 2659226	A 13-09-1991		
		AT 106707	T 15-06-1994		
		AU 7499191	A 10-10-1991		
		DE 69102369	D 14-07-1994		
		DE 69102369	T 05-01-1995		
		EP 0471821	A 26-02-1992		
		ES 2057874	T 16-10-1994		
		JP 4505574	T 01-10-1992		
		US 5314477	A 24-05-1994		
FR 2737656	A 14-02-1997	NONE			
EP 699426	A 06-03-1996	FR 2724109	A 08-03-1996		
US 5593445	A 14-01-1997	NONE			
WO 9310725	A 10-06-1993	AU 2954192	A 28-06-1993		
		US 5507816	A 16-04-1996		
FR 2718635	A 20-10-1995	NONE			
US 5782927	A 21-07-1998	WO 9819637	A 14-05-1998		
US 3795922	A 12-03-1974	NONE			
US 3426364	A 11-02-1969	DE 1807227	A 27-05-1970		
		GB 1243353	A 18-08-1971		
US 5425773	A 20-06-1995	US 5258031	A 02-11-1993		
		AU 7313394	A 23-10-1995		
		EP 0754018	A 22-01-1997		
		JP 10501705	T 17-02-1998		
		WO 9526697	A 12-10-1995		
		US 5562738	A 08-10-1993		
		ZA 9404507	A 14-02-1995		
US 5755796	A 26-05-1998	NONE			

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.